

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The Effectiveness of Mindfulness on Resilience and Assertiveness in Patients with Major Depressive Disorder

Protocol summary

Study aim

Determining the effect of mindfulness on resilience and Assertiveness in patient with Major Depressive Disorder

Design

A clinical trial with two test groups and a control group, one blind strain, randomized on 60 patients. A table of randomized numbers was used for randomization.

Settings and conduct

This clinical trial was conducted in Ibn Sina Psychiatric Hospital of Mashhad. 60 patients with major depressive disorder will be selected as a simple random sample and will be divided into two experimental and control groups. The experimental group (5 to 8 people)) will undergo 8 sessions of 90 minutes (3 sessions per week) of mindfulness training. The control group will receive the usual training during hospitalization. The summary of the training sessions will include: 30 minutes of body inspection exercises, 10 minutes of stretching exercises, 20 minutes of new topics, 10 minutes of mind presence on breathing, and 20 minutes of assigned task review. The method of blinding was one-way and the participants were blinded.

Participants/Inclusion and exclusion criteria

Entry conditions: participants must have a medical diagnosis of major depression; non-entry conditions: being illiterate

Intervention groups

The experimental group (5 to 8 people) will undergo 8 sessions of 90 minutes (3 sessions per week) of mindfulness training. The control group will receive the usual training during hospitalization.

Main outcome variables

Mindfulness increases resilience and Assertiveness in patients with major depressive disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230518058224N1**

Registration date: **2023-06-20, 1402/03/30**

Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**

Update count: **0**

Registration date

2023-06-20, 1402/03/30

Registrant information

Name

Ghazaleh Derakhshandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4220 8643

Email address

derakhshandeqazale@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Mindfulness on Resilience and Assertiveness in Patients with Major Depressive Disorder

Public title

"Effect of Mindfulness on Resilience and Assertiveness"

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having a diagnosis of major depressive disorder based on a psychiatrist's diagnosis Age 18 to 60 years The patient has passed the acute phase of the disease and is in the phase of mood stabilization Having at least reading and writing literacy Willingness to participate in the study Don't participate in the same training program

Exclusion criteria:

Do not attend two or more meetings A sudden change in the patient's mood Discharge of the patient

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random sampling of individuals who are selected by lottery.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants in the study were kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

No.4, Baharestan Dormitory, Medical Sciences Pardis, Bahonar Blvd., Vakil Abad Street, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2023-05-30, 1402/03/09

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.034

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Resilience score of Connor and Davidson's questionnaire, boldness score of Gambrill Rich questionnaire

Timepoint

Completing the assertiveness and resilience questionnaire before starting the intervention and four weeks after the end of the intervention.

Method of measurement

Connor and Davidson's Resilience Questionnaire, Gambrill Rich's Assertiveness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group (5 to 8 people) will undergo 8 sessions of 90 minutes (3 sessions per week) of mindfulness training. The training sessions will include: 30 minutes of body inspection exercises, 10 minutes of stretching exercises, 20 minutes of new topics, 10 minutes of mind presence on breathing, and 20 minutes of reviewing assigned assignments.

Category

Behavior

2

Description

Control group: The control group will receive the usual training during hospitalization

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina Hospital

Full name of responsible person

Saeed Vaghei

Street address

Ibn Sina Psychiatric Hospital, Hor Aamili Blvd.,
Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

919583134

Phone

+98 51 3711 2545

Email

derakhshandeqazale@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saeed Vaghei

Street address

No.4, Baharestan Dormitory, Medical Sciences Pardis,
Bahonar Blvd., Vakil Abad Street, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

nms.pr@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ghazaleh Derakhshandeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No.4, Baharestan Dormitory, Medical Sciences Pardis,
Bahonar Blvd., Vakil Abad Street, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 11 4220 8643

Email

derakhshandeqazale@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ghazaleh Derakhshandeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No.4, Baharestan Dormitory, Medical Sciences Pardis,
Bahonar Blvd., Vakil Abad Street, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 11 4220 8643

Email

derakhshandeqazale@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ghazaleh Derakhshandeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No.4, Baharestan Dormitory, Medical Sciences Pardis,
Bahonar Blvd., Vakil Abad Street, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 11 4220 8643

Email

derakhshandeqazale@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data freezes, such as primary outcome information, can be shared after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Study data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

People who are also engaged in the industry can apply to receive them.

From where data/document is obtainable

derakhshandeqazale@gmail.com

What processes are involved for a request to access data/document

The requester of these documents or data files can access the documents or data files by referring to the registered e-mail address and by introducing full details such as the field of study and the profession and the reason for accessing the data.

Comments